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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,730	03/11/2004	Chen Su	10209.478	4985

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EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1655	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,730	SU ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) *4-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are pending in the application.

Claims 4-6 were withdrawn from the merits as they are directed toward a non-elected invention.

Claims 1-3 were examined on their merits.

Morinda citrifolia may be referred to as 'MC' herein.

Drawings

The drawings are objected to because they should not be part of the Specification, and they should be numbered; e.g.; 'Figure 1', 'Figure 2'..... Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

Pages 28-69 of the Specification are in incorrect format. Applicant is asked to submit a new Specification incorporating the subject matter of pages 28-69 in proper Specification format because it appears that Applicant has submitted lab data as part of the Specification. Further, there are drawings in the Specification. The drawings should be present as a different pages than the Specification, and should be numbered accordingly (e.g., 'Figure 1', 'Figure 2'...). A brief description of the drawings needs to be added to the Specification which does not add New Matter to the Specification.

Appropriate correction is required.

Information Requirement Under 37 CFR 1.105

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application: In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

1) Knowledge of the amount: i.e., percentages or volume/volume of juices present in Tahitian noni juice/puree ® and other known compositions comprising *Morinda citrifolia* juice and other fruit juices besides *Morinda citrifolia* juice; e.g., blueberry juice and grape juice. If known, please disclose the amounts as compared to the entire composition, that is, volume of blueberry juice/volume of Tahitian noni juice/puree ® for example.

In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found

in applicant's disclosure.

The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-34 of copending Application No.**11/500,728**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 26-34 of '728 make obvious claims 1-3 in that they teach a method for inhibiting lipoxygenase with one ounce of a composition comprising MC juice and another juice between about 0.1-30%. Although '728 does not specifically teach the amount of MC juice as required by the claim, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Further, although the claims of '728 do not require the composition to be taken on an empty stomach, it is deemed that claims 1-3 are obvious in view of Gagnon (1997). Gagnon (1997) suggested '...taking extracts between meals, apart from food, because that is when they are more easily absorbed by the body. This way ,extracts enter the bloodstream readily and immediately start the healing process' (p.27).

The ordinary artisan would have been motivated to ingest the noni juice on an empty stomach in order to have allowed the juice to be absorbed by the body more readily, thereby obtaining the maximum medicinal benefit of the juice.

2. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-25 of copending Application No. **10/937,419**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 22-59 of '419 make obvious claims 1-3 in that they teach a method for treating comprising administering to a patient one ounce of a composition comprising MC juice and another juice between about 0.1-30%. Claim 59 of '419 specifically recites taking the medicament on an empty stomach. Although '419 does not specifically teach the amount of MC juice as required by the claim, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955).

see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

3. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. **10/808,872**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-52 of '872 make obvious claims 1-3 in that they teach a method for treating comprising administering to a patient one ounce of a composition comprising MC juice and another juice between about 0.1-30%. Claim 25 specifically recites taking the medicament on an empty stomach. Although '872 does not specifically teach the amount of MC juice as required by the claim, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined

4. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 and 67-69 of copending Application No..**10/396,868**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-52 and 67-69 of '868 make obvious claims 1-3 in that they teach a method for treating comprising administering to a patient one ounce of a composition comprising MC juice and another juice between about 0.1-30%. Claim 23 specifically recites taking the medicament on an empty stomach. Although '868 does not specifically teach the amount of MC juice as required by the claim, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined

5. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7, 10-26, 28, 30 and 32-68 of copending Application No.. US **10/335,653**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1, 3-7,

10-26, 28, 30 and 32-68 of '653 make obvious claims 1-3 in that they teach a method for treating comprising administering to a patient one ounce of a composition comprising MC juice and another juice between about 0.1-30%. Claim 24 specifically recites taking the medicament on an empty stomach. Although '653 does not specifically teach the amount of MC juice as required by the claim, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined

6. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-23 and 25-52 of copending Application No.**10/285,711**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 21-23 and 25-52 of '711 make obvious claims 1-3 in that they teach a method for treating comprising administering to a patient one ounce of a composition comprising MC juice and another juice between about 0.1-30%. Claim 27 specifically recites taking the medicament on an empty stomach. Although '711 does not specifically teach the amount of MC juice as required by the claim, it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined

7. Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-48 of copending Application No.**10/285,287**. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 15-48 of '287 make obvious claims 1-3 in that they teach a method for treating comprising administering to a patient one ounce of a composition comprising MC juice and another juice between about 0.1-30%. Claim 21 specifically recites taking the medicament on an empty stomach. Although '287 does not specifically teach the amount of MC juice as required by the claim, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal

concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined

Claim Rejections - 35 USC § 103

Claims 1-3 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bain(1999) in view of Moniz (US 5,288,491) *or* Bain (1999) in view of Gagnon (1997).

Applicant's arguments were fully considered, but not found persuasive.

Applicant's sole argument is that this rejection is rendered moot due to the amendment to the claims which inserts range limitations for the MC juice and non-MC juice. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-

effective variable which would have been routinely determined and optimized in the pharmaceutical art. Further, if there are any differences between Applicant's claimed method and that suggested by the combined teaching of the prior art, the differences would be appear minor in nature. Although the prior art does not teach the specific amounts of MC and non-MC juice, it would be conventional and within the skill of the art to identify the optional concentrations of juices in order to provide for a more palatable MC product.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

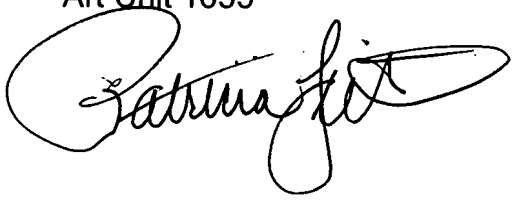
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655



January 5, 2006